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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/910,469	07/19/2001	Markus Schweitzer	264/217	1747

34263 7590 03/13/2003

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EXAMINER

FORMAN, BETTY J

ART UNIT

PAPER NUMBER

1634

DATE MAILED: 03/13/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/910,469

Applicant(s)

SCHWEITZER ET AL.

Examiner

BJ Forman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 July 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-326 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-326 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

Election/Restrictions

- I. Restriction to one of the following inventions is required under 35 U.S.C. 121:
1. Claims 1-65, drawn to a method for producing an array of immobilized nucleic acids, classified in class 435, subclass 287.2.
 2. Claims 66-101, drawn to a supermolecular construct comprising at least one synthetic address unit, at least two conjugates forming a synthetic binding system, classified in class 536, subclass 23.1.
 3. Claims 102-154, drawn to a conjugate comprising a nucleic acid and a synthetic binding unit, classified in class 536, subclass 23.1.
 4. Claims 155-188, drawn to a supermolecular construct comprising at least one conjugate and at least one synthetic address unit attached to a support and associated with at least one synthetic binding unit forming a synthetic binding system, classified in class 435 subclass 174.
 - 5-41. Claim 189, drawn to a conjugate comprising one of SEQ ID NO: 3, 5, 7, 9, 11, 13, 15, 17, 21, 23, 25, 27, 29, 31, 33, 35, 37, 39, 41, 43, 45, 47, 49, 51, 55, 57, 61, 63, 67, 69, 71, 73, or 75 and one of SEQ ID NO: 4, 6, 8, 10, 12, 14, 14, 16, 18, 20, 24, 26, 28, 30, 32, 34, 36, 38, 40, 42, 44, 46, 48, 50, 52, 54, 56, 58, 60, 62, 64, 66, 68, 70, 72, 74, or 76, classified in class 536, subclass 23.1.
 42. Claims 190-220, drawn to a method of producing a set of immobilized nucleic acids, classified in class 435, subclass 287.2.
 - 43-79. Claims 221-264, drawn to a unit of a synthetic binding system and kit comprising the unit wherein the unit comprises one of SEQ ID NO: 3, 5, 7, 9, 11, 13, 15, 17, 21, 23, 25, 27, 29, 31, 33, 35, 37, 39, 41, 43, 45, 47, 49, 51, 55, 57, 61, 63, 67, 69, 71, 73, or 75 and one of SEQ ID NO: 4, 6, 8, 10, 12, 14, 14,

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16, 18, 20, 24, 26, 28, 30, 32, 34, 36, 38, 40, 42, 44, 46, 48, 50, 52, 54, 56, 58, 60, 62, 64, 66, 68, 70, 72, 74, or 76, classified in class 536, subclass 23.1.

80. Claims 265-274, drawn to a method for preparing conjugates of nucleic acids, classified in class 435, subclass 91.1.

81. Claims 275-326, drawn to a method for enzymatically modifying a nucleic acid, classified in class 435, subclass 89.

II. The inventions are distinct, each from the other because of the following reasons:

a. Inventions 1 & 42 and 2-41 & 43-79 are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the products as claimed can be used in a materially different process i.e. the supermolecular constructs and conjugates of Inventions 2-41 and 43-79 can be used in a solution assay to isolate binding molecules.

b. Inventions 2-41 and 43-79 are independent and distinct supermolecular constructs and conjugates. The **Restriction** Requirement of Groups 2-41 and 43-79 is based upon the notice in the Official Gazette in October 1996 which states, "Applications claiming more than ten (10) individual independent and distinct nucleotide sequences in alternative form, such as set forth in example 1, will be subject to a **restriction requirement**. **This is a Restriction Requirement, not an election of species.**

By statute, "[I]f two or more independent and distinct inventions are claimed in one application, the Commissioner may require the application to be restricted to one of the inventions." 35 U.S.C. 121. Pursuant to this statute, the rules provide that "[I]f two or more independent and distinct inventions are claimed in a single application, the examiner in his action shall require the applicant...to elect that invention to which his claims shall be restricted." 37 C.F.R. 1.142(a). See also 37 C.F.R. 1.141.(a).

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Nucleotide sequences encoding different proteins are structurally distinct chemical compounds and are unrelated to one another. These sequences are thus deemed to normally constitute independent and distinct inventions within the meaning of 35 U.S.C. 121. While nucleic acid ligands are not coding sequences nevertheless they are structurally distinct chemical compounds differing in nucleotide sequences i.e. primary structure. Absent evidence to the contrary, each such nucleotide sequence is presumed to represent an independent and distinct invention, subject to a restriction requirement pursuant to 35 U.S.C. 121 and 37 C.F.R. 1.141.

- c. Inventions 80 & 81 and 2-41 & 43-79 are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the products as claimed can be made by a materially different process i.e. the supermolecules and conjugates of Inventions 2-41 and 43-79 can be made by isolating the nucleic acids from natural sources and followed by chemical modification in solution.
- d. Inventions 1, 42, 80 and 81 are independent and distinct methods. Inventions are independent and distinct if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions the inventions are not disclosed as capable of use together and they have different modes of operation and different functions. The methods of Invention 1 operates by activating locations on an array and contacting the locations with synthetic binding units and the method functions to produce an array of immobilized nucleic acids. The methods of Invention 42 operates by providing a support having addressable units and contacting at least two conjugates to the support and the method functions to produce a set of immobilized nucleic acids. The methods of Invention 80 operates by synthesizing conjugates on a solid support, treating the support with

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alkylamine followed by hydrazine and the method functions to prepare nucleic acid conjugates. The method of Invention 81 operates by contacting a conjugate with at least one nucleic acid enzyme and the method functions to enzymatically modify the nucleic acid.

III. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

IV. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

V. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Conclusion

VI. Any inquiry concerning this communication or earlier communications from the examiner should be directed to BJ Forman whose telephone number is (703) 306-5878. The examiner can normally be reached on 6:30 TO 4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones can be reached on (703) 308-1152. The fax phone numbers for the organization where this

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application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-8724 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



BJ Forman, Ph.D.
Patent Examiner
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March 10, 2003